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ABSTRACT

A hood or cap for a face mask breathing apparatus formed of flexible material having a narrow front piece which extends down the forehead of the wearer adjacent the nostril which merges into a wider back piece to encompass at least the rear of the head and the rear of the neck of the wearer the front piece and back piece being provided with straps to connect the hood to a face mask and correctly position and maintain the mask on the face of the wearer.

SUPPORT DEVICE

TECHNICAL FIELD

The present invention is generally directed to medical equipment, and in particular, support devices for securing breathing apparatus to the face of a patient. For example, the breathing apparatus could be a Continuous Positive Airway Pressure Mask, for which the support device secures the mask over the face of the patient.

BACKGROUND OF THE INVENTION

Sleeping disorders, such as sleep apnea, are common and potentially very serious conditions suffered by a large proportion of the population. Many products exist to provide relief to sufferers, usually in the form of providing a positive flow of air to the nose of the sufferer, hence the name, Continuous Positive Airway Pressure (CPAP) apparatus. This air flow is provided by means of a mask secured over the face and held in place by a support device, whilst the patient is asleep.

Typically, these support devices include adjustable straps which attach to the mask and wrap around the patient's head. Straps are used, rather than, say a rigid bracket, so that when the patient sleeps with his head to the side, the straps are thin enough so as not to press against the patient's head, and thus be intolerably uncomfortable. Straps, however, must act in tension, and therefore must act in a straight line to apply the required force to hold the mask in place. Unfortunately, the required angle of the strap to comfortably wrap around the head may be different to the angle for which the straps attach to the mask. This, combined with the reduced friction of the strap against the patient's hair, will tend to permit the strap to shift position during the night, as the strap balances the forces from the mask attachment to the position on the patient's head.

As the straps shift, the mask will also tend to shift position, and generally, the mask and straps will be unstable. The patient is therefore going to suffer further by being uncomfortable or by awakening to re-adjust the position of the mask during the night. A typical circumstance is for the patient to remove the mask altogether. In any case, any benefit provided by the CPAP apparatus is negated by the support device, through interrupted sleep.

Moreover, because the straps are reasonably thin and must be suitably

tight to ensure sealing of the mask over the face, the discomfort of the patient is further increased by the localized pressure applied to the back of the head by the straps.

In addition to the combination of mask and support device described above, the CPAP apparatus also includes the proprietary machine used to drive the airflow, and the tubing which delivers the airflow from the machine to the mask. In cases where a sleeping disorder is being diagnosed under controlled conditions, there may also be a series of transducers attached to the patient providing heart rate, respiration, encephalographic data *etc.* Each of these will be associated with cabling to corresponding data acquisition devices. Whether under normal or clinical conditions, fundamentally, the CPAP apparatus connects the patient to remote equipment, fixed in place.

It follows that, if left unrestrained, there is a risk the tubing will become tangled as the patient moves in his sleep. Alternatively, and the method often recommended, the tubing is fixed to the bed head, or similar, and thus be free from tangling. This, however, does not alleviate the problem of relative movement between the patient and the bed, and in this case, the effect is analogous to the patient being tied to the bed like a dog to a post.

Functionally, the mask's efficiency is dependent on maintaining the required air pressure in the airways and lungs of the patient. Thus, the seal between the face and the mask is extremely important, so that the air pressure is not lost. Of equal importance is the avoidance of air pressure being lost due to the patient's mouth opening. It follows that the efficiency of the CPAP apparatus is of no consequence if the support device provides a level of discomfort that drives the patient to remove the mask altogether.

It is therefore an object of the present invention to limit one or more of the problems associated with the prior art.

STATEMENT OF INVENTION

With this in mind, the invention provides a support device for a mask including a load distribution means for fitting to a patient's head, fitting to at least the bowl of the patient's head;

a first pair of elongate attachment means for selective attachment to that portion of the mask which is below the nose, and integrally connected to a

proximate edge of the load distribution means, such that each elongate attachment means is located on either side of the head;

and a second set of elongate attachment means for selective attachment to that portion of the mask which is above or adjacent to the nose, and integrally connected to another proximate edge of the load distribution means;

wherein when the first and second elongate attachment means are attached to the mask and subsequently tensioned, the load distribution means distributes the tension force in the form of a pressure applied over a substantial area of the patient's head, and

wherein the support device includes a mouth closing means.

Thus, to further enhance the efficiency of the apparatus, the mouth can be biased closed during sleep, and be part of the support device.

Unlike conventional support devices, the unbalanced forces caused by the difference in angles between the elongate attachment means at the connection to the mask and elongate attachment means in contact with the head, are distributed by the load distribution means, rather than through a shifting of position of the elongate attachment means. Further, the load distribution means may act to restrain the elongate attachment means from moving, should there be additional forces applied to the elongate attachment means. Thus, not only does the greater frictional grip the load distribution means has to the patient's head hinder movement, but so does the balance of forces between the first and second elongate attachment means, acting through the load distribution means.

Preferably, the load distribution means is a cap shaped to fit the bowl of the patient's head. Thus, the load distribution function of this feature works through a tensile membrane effect, and having the added advantage of comfortable fitting and ease of manufacture.

Preferably, the elongate attachment means are straps.

Preferably, the elongate attachment means are cords having enlarged end portions for attachment to the mask.

Preferably the load distribution means may include an integrally connected tube restraint means.

The tube restraint means would function to hold the tubes free from tangling with the patient as he moves in his sleep, and making a connection to the

bed head redundant. Thus, the patient is permitted free movement in the bed while avoiding the tangling problems of the past.

Preferably, the load distribution means is at least one ring of broad material that if shaped to fit the bowl of the patient's head within the hole defined by the ring.

Preferably, the second elongate attachment means may consist of a single strap. Thus, the invention is equally effective for those CPAP masks that have a single upper attachment means, rather than two.

Preferably the first and second elongate attachment means are made from an elastic hook and loop fastener (Velcro $_{TM}$ or Velstretch $_{TM}$) material. Thus the elongate attachment means can be used for selective attachment without the use of attachment buckles or adjustment buckles, both of which may press into the patient's face or head.

More preferably, the mouth closing means may be attached to the first elongate attachment means. By attaching to the first elongate attachment means, an upward force to close the mouth may be balanced against the first elongate attachment means, which are in turn restrained by the load distribution means. Thus, a substantial force may be applied to close the mouth without detracting from the function of the support device.

Even more preferably, the mouth closing means may be selectively adjustable to fit a wide range of uses and patients.

Even more preferably, the mouth closing means may be a strip of material spanning between each of the first elongate attachment means.

Even more preferably, such a strip may be in the form of a sheet of material that may grip around the jaw and chin, or a simple chin strap.

Even more preferably, the strip may be made of an elastic material.

Preferably, the tube restraint means may be a loop of material through which the tubing, or cables if necessary, may be passed. Thus, where the patient moves in his sleep, the tubing is held away from his body, and the tubing may slide freely to accommodate the change in distance between the patient and the CPAP apparatus.

Preferably, the tube restraint means may be a member that engages the tubing, and thus prevents free sliding of the tubing. The engagement may be

through friction or a positive engagement. In certain circumstances, it may be useful to have the tubing fixed to the load distribution means by the tube restraint means, and so where the patient's movement may vary the tension in the tubing from the CPAP apparatus to the load distribution means, the slack in the tube remains substantially unchanged during such movement, and thus avoids applying undue forces to the mask or the tubing.

BRIEF DESCRIPTION OF THE DRAWINGS

It will be convenient to further describe the present invention with respect to the accompanying drawings which illustrate possible arrangements of the invention. Other arrangements of the invention are possible, and consequently the particularity of the accompanying drawings is not to be understood as superseding the generality of the preceding description of the invention.

Figure 1 is a plan view of a support device, according to the present invention; and

Figure 2 is a side elevation of the device of Figure 1.

DESCRIPTION OF PREFERRED EMBODIMENTS

Figure 1 shows a support device 1 for a CPAP mask 10, comprising a skull cap 2, a pair of straps 3a and 3b extending from an edge of the skull cap 2 and a further pair of straps 4a and 4b extending from an opposing edge of the skull cap 2. At the end of each of the straps are tabs 7 and 8 which can be used to engage the CPAP mask 10 by looping the tabs 7 and 8 through strap fixation brackets (not shown) on the CPAP mask 10.

A further feature of the invention is a loop 6 which is connected to the top face of the skull cap 2 and adjacent the edge to which one pair of straps 3a and 3b is connected. The loop 6 is of sufficient size so as to allow tubing 12 to fit through the loop 6.

A still further feature is a chin strap 5 which is attached to the support device 1 by a sliding connection with the straps 4a and 4b. Each of the chin strap loops 9a and 9b slide along one of the straps 4a and 4b, and thus forms a bridge between the two straps 4a and 4b. The chin strap 5 is also made from an elastic hook and loop fastener (Velcro $_{TM}$), which provides both elastic adjustment and also comfort for the patient.

Figure 2 shows the support device 1 being worn by a patient 13. The skull cap 2 is positioned on the bowl 15 of the patient's head 13. The straps 3a and 3b are connected to upper strap fixation brackets (not shown) on the CPAP mask 10. The chin strap 5 is connected to the straps 4a and 4b, which are then connected to lower strap fixation brackets (not shown) on the CPAP mask 10. The tubing 12, which supplies air to maintain the positive air pressure in the patient's airways and lungs, is passed through the loop 6 and consequently directs the tubing away from the patient's face.

The support device 1, with CPAP mask 10 attached, is then slipped over the patient's head 13 and the CPAP mask 10 fitted over the nose 14. Once in place, the straps 3a, 3b, 4a and 4b are adjusted to provide the desired mask pressure on the patient's face. As the straps 3a, 3b, 4a and 4b are all connected to the skull cap 2, as the adjustments are made, the various tensile forces in the straps 3a, 3b, 4a and 4b are balanced by minor positional adjustments of the skull cap 2.

As a final adjustment, the chin strap 5 is positioned under the chin such that a force is directed upwards to the chin. By adjusting the straps 4a and 4b, the chin strap 5 can be tightened to ensure the patient's mouth remains closed during sleep. Conveniently, the arrangement of the chin strap 5 and the straps 4a and 4b can be adjusted so that the straps 4a and 4b are realigned to fit under the patient's ears 17. Again, because of the balancing effect caused by the skull cap 2, this realignment of the straps 4a and 4b does not interfere with the function of the support device 1.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A support device for a mask including a load distribution means for fitting to a patient's head, fitting to at least the bowl of the patient's head;

a first pair of elongate attachment means for selective attachment to that portion of the mask which is below the nose, and integrally connected to a proximate edge of the load distribution means, such that each elongate attachment means is located on either side of the head;

and a second set of elongate attachment means for selective attachment to that portion of the mask which is above or adjacent to the nose, and integrally connected to another proximate edge of the load distribution means;

wherein when the first and second elongate attachment means are attached to the mask and subsequently tensioned, the load distribution means distributes the tension force in the form of a pressure applied over a substantial area of the patient's head; and

wherein the support device includes a mouth closing means.

2. A support device according to claim 1, wherein the elongate attachment means are straps.

3. A support device according to claim 1, wherein the elongate attachment means are cords having enlarged end portions for attachment to the mask.

4. A support device according to any one of the preceding claims, wherein the load distribution means is at least one ring of broad material shaped to fit the bowl of the patient's head within the hole defined by the ring.

5. A support device according to claim 1, wherein the second elongate attachment means consists of a single strap.

6. A support device according to any one of the preceding claims, wherein the first and second elongate attachment means are made of elastic hook and loop fastener material.

7. A support device according to any one of the preceding claims, wherein the mouth closing means is attached to the first elongate attachment means.

8. A support device according to any one of the preceding claims, wherein the mouth closing means is selectively adjustable.

9. A support device according to any one of the preceding claims, wherein the mouth closing means includes a strip of material spanning between each of the first elongate attachment means.

10. A support device according to claim 9, wherein the strip is in the form of a sheet of material to grip around the jaw and chin, or act as a simple chin strap.

11. A support device according to claim 9 or 10, wherein the strip is made of an elastic material.

12. A support device according to any one of the preceding claims, wherein the load distribution means includes an integrally connected tube restraint means.

13. A support device according to any one of the preceding claims, wherein the tube restraint means includes a loop of material through which the tubing and optionally cables pass.

14. A support device according to claim 13, wherein the tube restraint means includes a member that engages the tubing to restrict free sliding of the tubing.

15. A support device substantially as hereinbefore described with reference to Figures 1 and 2.

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Figure 1

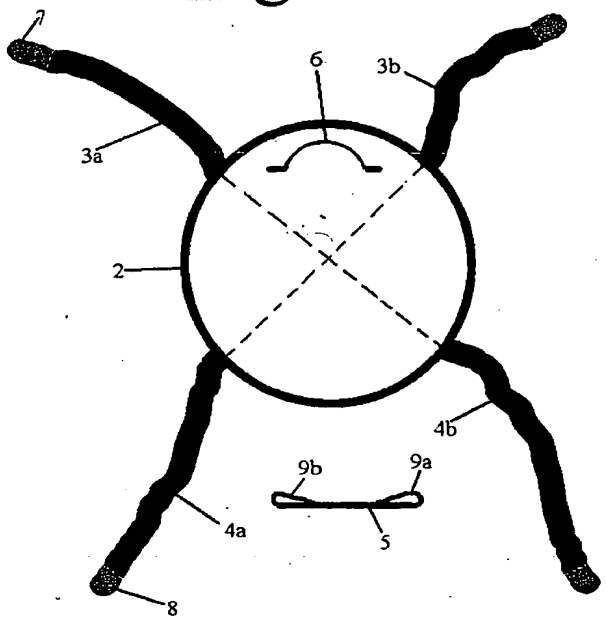

Figure 2